



UNITED STATES  
PATENT AND  
TRADEMARK OFFICE

AUG 10 2001

UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY  
AND DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
WWW.USPTO.GOV

#20

NIXON & VANDERHYDE P.C.  
1100 NORTH GLEBE ROAD, 8TH FL.  
ARLINGTON, VA 22201-4714

In re Application of :  
Michael J. Elmore et al :  
Serial No.: 08/981,087 : PETITION DECISION  
Filed: May 27, 1998 :  
Attorney Docket No.: 124-688 :

This is in response to applicants' petition under 37 CFR 1.181, which is being treated as a petition under 37 CFR 1.144, filed January 7, 2000, requesting withdrawal of an improper Lack of Unity requirement. The delay in acting on this petition is regretted, however the petition was only recently brought to the attention of the deciding official.

A review of the file history shows that this application was filed under 35 U.S.C. 371 as the National Phase of PCT/GB96/01409 on December 12, 1997, and accorded a filing date when all required elements were filed on May 27, 1998. The examiner upon taking the application up for examination mailed a Sequence compliance requirement letter accompanied by a Lack of Unity requirement to applicants on June 16, 1999, setting forth two groups of inventions, as follows:

Group I - claims 1-12 and 19-24, drawn to polypeptides free of botulinum toxin activity, the polypeptide composition and vaccine comprising the polypeptide;  
Group II - claims 13-18 and 25, drawn to recombinant DNA encoding a polypeptide and method of producing same.

The examiner reasoned that the two groups lacked a corresponding special technical feature and further that they have different structural and biological properties in that Group I is directed to acids (polypeptides) and Group II is directed to nucleotides. The examiner also noted that the polypeptide did not make a contribution over the prior art referencing Current Microbiology 29:69-77 (1994) as evidence that the polypeptide is known. Applicants replied on September 14, 1999, electing with traverse Group I and arguing that the International Search Report found no Lack of Unity. In a new Office action, mailed October 7, 1999, the examiner maintained the Lack of Unity for the reasons previously set forth and made the requirement Final. The examiner also rejected the claims under 35 U.S.C. 101, 35 U.S.C. 102(b) and 35 U.S.C. 112, first and second paragraphs. Applicants replied on January 7, 2000, amending a number of claims and traversing the Lack of Unity requirement based on Example 17 of the PCT Administrative Instructions, Annex B, which indicates that a protein and the DNA sequence encoding the protein are considered to have unity of invention. This petition was concurrently filed. In a non-Final Office action mailed March 16, 2000, the examiner maintained the Lack of Unity requirement for the

same reasons as before reiterating that the polypeptide does not make a contribution over the prior art as evidenced by the Current Microbiology reference cited previously and therefore unity is lacking between the polypeptide and the protein encoded thereby. The examiner further rejected the elected claims under 35 U.S.C. 101, 35 U.S.C. 112, first and second paragraphs, and 35 U.S.C. 102(a) and 103(b). As new rejections were made, the action was not made Final.

Applicants replied on June 16, 2000, amending several claims, canceling claims 1-2 and adding claim 26. Applicants also requested an immediate decision on the petition filed with the previous response with regard to the Lack of Unity requirement. A supplemental amendment was filed June 19, 2000, adding claims 27-33. On February 27, 2001, the examiner mailed a Notice to Comply with Sequence requirements by supplying SEQ ID NOS in the claims. Applicants replied on March 27, 2001, by amending those claims containing sequences by adding SEQ ID NOS. On June 5, 2001, the examiner mailed a Final Office action to applicants in which the restriction requirement was maintained and the elected claims were rejected under 35 U.S.C. 112, first and second paragraphs, and 35 U.S.C. 102(a) and 102(b) over various references. Subsequent to the mailing of the Office action the application was forwarded for decision on the petition.

## DISCUSSION

Restriction/Lack of Unity requirements in National Phase applications filed under 35 U.S.C. 371 are governed by application of PCT Rule 13.1 and 13.2 which are further explained in Annex B of the Administrative Instructions. In traversing the requirement applicants cite M.P.E.P. 1893.03(d), in part. The third paragraph quoted is as follows:

The principles of unity of invention are used to determine the types of claimed subject matter and the combinations of claims to different categories of invention that are permitted to be included in a single international or national stage patent application. The basic principle is that an application should relate to only one invention or, if there is more than one invention, that applicant would have a right to include in a single application only those inventions which are so linked as to form a single general inventive concept. A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. **The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.** For example, a corresponding technical feature is exemplified by a key defined by certain claimed structural characteristics which correspond to the claimed features of a lock to be used with the claimed key. Note also examples 1-17 of Annex B Part 2 of the PCT Administrative Instructions as amended July 1, 1992 contained in Appendix AI of the MPEP.

This mirrors part (b) of Annex B, which reads as follows:

(b) Technical Relationship. Rule 13.2 defines the method for determining whether the requirement of unity of invention is satisfied in respect of a group of inventions claimed in an international application. Unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. **The expression special technical features is defined in Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.** The determination is made on the contents of the claims as interpreted in light of the description and drawings (if any).

Applicants also reference and quote from Example 17 of Annex B, as follows:

Expression of the DNA sequence in a host results in the production of a protein which is determined by the DNA sequence. **The protein and the DNA sequence exhibit corresponding special technical features.**

Note the highlighted portions of the above three citations. It is clearly stated in the first two citations that the "special technical feature" is that which makes a contribution over the prior art (i.e. is novel or unobvious). Also the same special technical features must be present or a part of each of the inventions in order for Unity to be found. In the quote from example 17 Unity is based on the finding of corresponding "special technical features" which define over the prior art. If this were not so, there would be no Unity.

In the above identified application the examiner has made a holding of Lack of Unity between the polypeptide and the DNA encoding the polypeptide based on evidence that the polypeptide is known and thus does not make a contribution over the prior art. As evidence that the polypeptide does not make a contribution over the prior art, the article in Current Microbiology is initially cited. In subsequent Office actions other patent and literature references are cited showing that the polypeptide is known. Thus the polypeptide which is the special technical feature which is common to each invention does not make a contribution over the prior art. In view of this showing by the examiner it must be concluded that Unity is Lacking. With respect to applicants' argument that no Lack of Unity was found in the International Phase, PCT Rules allow review of any Unity or Lack of Unity holding at each stage of prosecution. The determination may, therefore, change with each Office action depending on the prior art discovered and applicants' actions. Such is no different from restriction practice in regularly filed applications where the examiner reviews the restriction requirement for correctness with each Office action. It should also be noted that even when there is not Unity in a PCT application inventions which lack Unity may continue to be searched and/or examined together.

## DECISION

Applicants' petition is **DENIED** for the reasons set forth above

Any request for reconsideration of this decision or a renewed petition must be filed within TWO MONTHS of the mailing date of this decision in order to be considered timely and must be directed to the Assistant Commissioner of Patents.

Should there be any questions with respect to this decision, please contact William R. Dixon, Jr., by mail addressed to: Director, Technology Center 1600, Washington, D.C. 20231, or by telephone at (703)308-3824 or by facsimile transmission at (703) 305-7230.

*Jasemine C. Chambers*  
Jasemine C. Chambers  
Director, Technology Center 1600